BILLING Code: 4150-28-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Request for Information: Solicits Public Input on the Renewal of "Combating the Silent

Epidemic of Viral Hepatitis, Action Plan for the Prevention, Care, and Treatment of Viral

Hepatitis"

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of the

Assistant Secretary for Health.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) is seeking broad public

input as it begins efforts to renew the 2011 Action Plan for the Prevention, Care, and Treatment

of Viral Hepatitis to include actions which can be undertaken over the course of the next three

years, 2014 - 2016.

DATES: To be assured consideration, comments must be received at one of the addresses

provided below, no later than 5:00 p.m. EST on [INSERT DATE 30 DAYS FOLLOWING

DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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ADDRESSES: Electronic responses are strongly preferred and may be addressed to **Corinna.Dan@hhs.gov.** Written responses should be addressed to: U.S. Department of Health and Human Services, 200 Independence Ave., SW, Room 443-H, Washington, DC 20201. Attention: 2014 Viral Hepatitis Action Plan.

FOR FURTHER INFORMATION CONTACT: Corinna Dan, RN, MPH, Office of HIV/AIDS and Infectious Disease Policy, (202) 401-9581.

SUPPLEMENTARY INFORMATION: On May 12, 2011, the U.S. Department of Health and Human Services (HHS) issued *Combating the Silent Epidemic of Viral Hepatitis: Action Plan for the Prevention, Care, and Treatment of Viral Hepatitis* (Action Plan). The Action Plan details more than 150 actions to be undertaken over the course of three years by agencies and offices across HHS and partners at the Federal Bureau of Prisons, the U.S. Department of Veterans Affairs, and the U.S. Department of Housing and Urban Development that will improve the prevention, diagnosis, and treatment of viral hepatitis in the United States. A copy of the Action Plan and the Viral Hepatitis Action Plan Interagency Implementation Progress Report--Year 1 are available at http://www.aids.gov/news-and-events/hepatitis/.

The Action Plan put a spotlight on this silent epidemic and its growing impact in the United States, where as many as 5.3 million persons are living with chronic hepatitis B or C infection and millions more are at risk of infection. While viral hepatitis has been addressed by various federal research, prevention, care, and treatment programs, much of this work has been conducted independently, sometimes in isolation from other related efforts. Following the

Institute of Medicine's (IOM) 2010 report, *Hepatitis and Liver Cancer*, which recommended steps to reduce the threats posed by hepatitis B and hepatitis C, Dr. Howard K. Koh, Assistant Secretary for Health, convened an interagency workgroup composed of subject matter experts from various HHS agencies to review the IOM recommendations and develop a comprehensive strategic viral hepatitis action plan that would:

- address IOM recommendations for viral hepatitis prevention, care, and treatment;
- set forth actions to improve viral hepatitis prevention and ensure that infected persons are identified and provided care and treatment; and,
- improve coordination of all activities related to viral hepatitis across HHS and promote collaborations with other government agencies and nongovernmental organizations.

Critical input into the Action Plan was also provided by stakeholders from other federal agencies, professional societies, and state, local, and community partners. The actions presented in the Action Plan represent efforts to be undertaken in calendar year 2011, 2012, or 2013. Some of the actions outlined in the Action Plan can be accomplished by using existing resources through improved coordination and integration, while others are subject to the availability of funds.

The Action Plan is organized into six priority areas which correspond to the 2010 IOM recommendations:

Priority 1 Educating Providers and Communities to Reduce Health Disparities

- GOAL 1.1 Build a U.S. health care workforce prepared to prevent and diagnose viral hepatitis and provide care and treatment to infected persons.
- GOAL 1.2 Decrease health disparities by educating communities about the benefits of viral hepatitis prevention, care, and treatment.

Priority 2 Improving Testing, Care, and Treatment to Prevent Liver Disease and Cancer GOAL 2.1 Identify persons infected with viral hepatitis early in the course of their disease.

- GOAL 2.2 Link and refer persons infected with viral hepatitis to care and treatment.
- GOAL 2.3 Improve access to and quality of care and treatment for persons infected with viral hepatitis.
- GOAL 2.4 Advance research to facilitate viral hepatitis prevention and enhance care and treatment for infected persons.

Priority 3 Strengthening Surveillance to Detect Viral Hepatitis Transmission and Disease

- GOAL 3.1 Build a network of state and local surveillance systems with sufficient capacity to monitor viral hepatitis transmission and disease.
- GOAL 3.2 Monitor viral-hepatitis-associated health disparities.
- GOAL 3.3 Monitor provision and impact of viral hepatitis prevention, care, and treatment services.
- GOAL 3.4 Develop and implement new technologies and laboratory procedures to improve viral hepatitis surveillance.

Priority 4 Eliminating Transmission of Vaccine-Preventable Viral Hepatitis

- GOAL 4.1 Eliminate mother-to-child transmission of hepatitis B.
- GOAL 4.2 Achieve universal hepatitis A and B vaccination for vulnerable adults.
- GOAL 4.3 Design and test new or improved viral hepatitis vaccines and determine the indications for their optimal use.

Priority 5 Reducing Viral Hepatitis Caused by Drug Use Behaviors

- GOAL 5.1 Ensure that persons who inject drugs have access to viral hepatitis prevention, care, and treatment services.
- GOAL 5.2 Mobilize community resources to prevent viral hepatitis caused by injection drug use.
- GOAL 5.3 Provide persons who inject drugs with access to care and substance abuse treatment to prevent transmission and progression of disease.
- GOAL 5.4 Expand access to and delivery of hepatitis prevention, care, and treatment services in correctional settings.
- GOAL 5.5 Advance research to improve prevention of viral hepatitis among persons who use drugs.

Priority 6 Protecting Patients and Workers From Health Care-Associated Viral Hepatitis

- GOAL 6.1 Reduce transmission of viral hepatitis to patients resulting from misuse of medical devices and drugs.
- GOAL 6.2 Reduce iatrogenic transmission of viral hepatitis associated with blood, organs, and tissues.
- GOAL 6.3 Reduce occupational transmission of viral hepatitis.
- GOAL 6.4 Enhance understanding of the preventable causes of viral hepatitis transmission in health care settings.

Following the Action Plan's release, agencies and offices across HHS began working to implement the actions assigned to them in the Action Plan. To support these efforts, HHS convened a Viral Hepatitis Action Plan Implementation Group (VHIG) and charged it with coordinating, supporting, and overseeing activities related to the Action Plan. The VHIG

comprises representatives from across HHS and other federal agencies and is chaired by Dr. Ronald Valdiserri, Deputy Assistant Secretary for Health, Infectious Diseases.

The opportunity provided by the renewal of the Action Plan for the Prevention, Care, and Treatment of Viral Hepatitis for 2014, 2015, 2016 offers many benefits such as:

- identification of measures to assess progress on addressing viral hepatitis in the U.S.;
- identification of gaps in viral hepatitis services and data;
- inclusion of new input from stakeholders;
- recommendations for effective viral hepatitis program models; and,
- application of lessons learned since the release of the 2011 Action Plan.

Accordingly, this request for information seeks public comment on several key dimensions of a renewed Action Plan for the Prevention, Care, and Treatment of Viral Hepatitis, including but not limited to the following:

- 1. Considering the six priority areas and related goals, please respond to the following questions:
 - a. Are there critical gaps in viral hepatitis activities which should be given a major focus in a renewed Action Plan? Provide background and rationale for their inclusion. These gaps may have been included in the 2011 Viral Hepatitis Action Plan or they may be new.
 - b. Are there effective models and best practices that should be considered for replication? Please include rationale for their use in the field/area of viral hepatitis.

2. What are the specific measures that should be used to track progress of implementation of

the Viral Hepatitis Action Plan and/or the progress of addressing the epidemics of viral

hepatitis? Provide background and rationale for the use of these measures.

3. What specific activities within and/or components of the Affordable Care Act offer

substantial opportunities to support improved viral hepatitis health care services and

data? Describe how this might evolve.

4. How can government better engage with non-governmental stakeholders around the

implementation of the National Viral Hepatitis Action Plan? Provide

examples/suggestions of how this could be integrated into a renewed Action Plan and its

implementation.

5. What additional information not specifically addressed elsewhere in this RFI that would

be important for the government to bear in mind in developing a renewed National Viral

Hepatitis Action Plan?

DATED: May 21, 2013

Ronald O. Valdiserri,

Deputy Assistant Secretary for Health, Infectious Diseases

Office of the Assistant Secretary for Health

[FR Doc. 2013-13332 Filed 06/04/2013 at 8:45 am; Publication Date: 06/05/2013]

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